

THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Fallaux et al.

Serial No.: 10/038,271

Filed: October 23, 2001

For: PACKAGING SYSTEMS FOR

HUMAN RECOMBINANT ADENOVIRUS

TO BE USED IN GENE THERAPY

Confirmation No.: 8381

Examiner: D. Nguyen

Group Art Unit: 1632

Attorney Docket No.: 2578-3833.6US

CERTIFICATE OF MAILING

I hereby certify that this correspondence along with any attachments referred to or identified as being attached or enclosed is being deposited with the United States Postal Service as First Class Mail on the date of deposit shown below with sufficient postage and in an envelope addressed to the Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

August 10, 2005

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SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Mail Stop Amendment Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Sir:

In compliance with the duty to disclose information material to patentability pursuant to 37 C.F.R. § 1.56, it is respectfully requested that this Supplemental Information Disclosure Statement be entered and the documents listed on attached Form PTO/SB/08 be considered by the Examiner and made of record. Copies of the listed documents are enclosed pursuant to 37 C.F.R. § 1.98(a).

Serial No.: 10/038,271

Other Documents

ACSADI et al., Adenovirus-mediated gene transfer into striated muscles, J Mol Med, 1995, pp. 165-80, Vol. 73.

BERG et al., High-Level Expression of Secreted Proteins from Cells Adapted to Serum-Free Suspension Culture, BioTechniques, 1993, pp. 972-78, Vol. 14, No. 6.

COLBY et al., Adenovirus Type 5 Virions Can Be Assembled In Vivo in the Absence of Detectable Polypeptide IX, Journal of Virology, Sept. 1981, pp. 997-80, Vol. 39, No. 3.

GALLIMORE et al., Transformation of Human Embryo Retinoblasts with Simian Virus 40, Adenovirus and ras Oncogenes, Anticancer Research, 1986, pp. 499-508, Vol. 6.

GenBank Accession No. X02996.1, 1993, "Adenovirus type 5 left 32% of the genome."

GRAHAM et al., Size and location of the transforming region in human adenovirus type 5 DNA, Nature, October 25, 1974, pp. 687-91, Vol. 251.

HITT et al., Construction and Propagation of Human Adenovirus Vectors, Cell Biology, 1994, pp. 479-90, Vol. 1, Academic Press, San Diego, California.

MARCK, CHRISTIAN, 'DNA Strider': a 'C' program for the fast analysis of DNA and protein sequences on the Apple Macintosh family of computers, Nucleic Acids Research, 1988, pp. 1829-36, Vol. 16, No. 5.

MITANI et al., Rescue, propagation, and partial purification of a helper virus-dependent adenovirus vector, Proc. Natl. Acad. Sci., April 1995, pp. 3854-58, Vol. 92.

NCBI database excerpt: Locus AC_000008 (human adenovirus type 5)

Notice of Opposition to a European Patent by Serono International S.A. filed against Patent No. 0 833 934 (July 5, 2005).

Opposition lodged by Cevec Pharmaceuticals GmbH against European Patent 0 833 934 (July 5, 2005).

PESHWA et al., Cultivation of Mammalian Cells as Aggregates in Bioreactors: Effect of Calcium Concentration on Spatial Distribution of Viability, 1993, pp. 179-87, Vol. 41.

PRELICH et al., Functional Characterization of Thermolabile DNA-Binding Proteins That Affect Adenovirus DNA Replication, Journal of Virology, Mar. 1986, pp. 883-92, Vol. 57, No. 3.

Serial No.: 10/038,271

RAO et al., The adenovirus E1A proteins induce apoptosis, which is inhibited by the E1B 19-kDa and Bc1-2 proteins, Proc. Natl. Acad. Sci., August 1992, pp. 7742-46, Vol. 89.

RHIM, JOHNG S., Development of Human Cell Lines from Multiple Organs, 2000, Annals New York Academy of Sciences, pp. 16-25.

ROWE et al., Establishment and Characterization of Hamster Cell Lines Transformed by Restriction Endonuclease Fragments of Adenovirus 5, Journal of Virology, Jan. 1984, pp. 162-70, Vol. 49, No. 1.

RULEY, H. EARL, Adenovirus early region 1A enables viral and cellular transforming genes to transform primary cells in culture, Nature, August 1983, pp. 602-06, Vol. 304.

SAMBROOK et al., Molecular Cloning -- A Laboratory Manual, 3rd edition, 2001, Cold Spring Harbor Laboratory Press, Cold Spring Harbor, New York.

WHITE et al., Adenovirus E1B 19-Kilodalton Protein Overcomes the Cytotoxicity of E1A Proteins, Journal of Virology, June 1991, pp. 2968-78, Vol. 65, No. 6.

WHITE et al., Role of Adenovirus E1B Proteins in Transformation: Altered Organization of Intermediate Filaments in Transformed Cells That Express the 19-Kilodalton Protein, Molecular and Cellular Biology, Jan. 1990, pp. 120-30, Vol. 10, No. 1.

WHITE et al., Specific disruption of intermediate filaments and the nuclear lamina by the 19-kDa product of the adenovirus E1B oncogene, Proc. Natl. Acad. Sci., December 1989, pp. 9886-90, Vol. 86.

WHITE et al., The 19-Kilodalton Adenovirus E1B Transforming Protein Inhibits Programmed Cell Death and Prevents Cytolysis by Tumor Necrosis Factor alpha, Molecular and Cellular Biology, June 1992, pp. 2570-80, Vol. 12, No. 6.

WOODWORTH et al., Transformation of Differentiated Rat Hepatocytes with Adenovirus and Adenovirus DNA, Journal of Virology, Nov. 1987, pp. 3570-79, Vol. 61, No. 11.

Serial No.: 10/038,271

This Supplemental Information Disclosure Statement is filed after the mailing date of the first Office Action on the merits.

I hereby certify that each item of information contained in this Supplemental Information Disclosure Statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the statement, and therefore no fee is due.

Respectfully submitted,

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ACT/bv

Enclosures: Form PTO/SB/08

Copy of documents cited

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PTO/SB/08B(10-03)

Approved for use through 7/31/2006. OMB 0651-0031

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| DIEGO | N C A COLONY | DICCI OCUDI | Application Number | 10/038,271 | | |
| | | DISCLOSUR | riling Date | October 23, 2001 | | |
| STATE | MENT BY | APPLICANT | First Named Inventor | Fallaux et al. | | |
| | | | Group Art Unit | 1632 | | |
| (use as many sheets as necessary) | | | Examiner Name | D. Nguyen | | |
| Sheet | 1 | of 2 | Attorney Docket Number | 2578-3833 6US | | |

| | | NON PATENT LITERATURE DOCUMENTS | |
|------------------------|--------------|---|----|
| Examiner Initials * | Cite No.1 | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published. | T² |
| | | ACSADI et al., Adenovirus-mediated gene transfer into striated muscles, J Mol Med, 1995, pp. 165-80, Vol. 73. | |
| | | BERG et al., High-Level Expression of Secreted Proteins from Cells Adapted to Serum-Free Suspension Culture, BioTechniques, 1993, pp. 972-78, Vol. 14, No. 6. | |
| | | COLBY et al., Adenovirus Type 5 Virions Can Be Assembled In Vivo in the Absence of Detectable Polypeptide IX, Journal of Virology, Sept. 1981, pp. 997-80, Vol. 39, No. 3. | |
| | | GALLIMORE et al., Transformation of Human Embryo Retinoblasts with Simian Virus 40, Adenovirus and ras Oncogenes, Anticancer Research, 1986, pp. 499-508, Vol. 6. | |
| | | GenBank Accession No. X02996.1, 1993, "Adenovirus type 5 left 32% of the genome." | |
| | | GRAHAM et al., Size and location of the transforming region in human adenovirus type 5 DNA, Nature, October 25, 1974, pp. 687-91, Vol. 251. | |
| | | HITT et al., Construction and Propagation of Human Adenovirus Vectors, Cell Biology, 1994, pp. 479-90, Vol. 1, Academic Press, San Diego, California. | |
| | | MARCK, CHRISTIAN, 'DNA Strider': a 'C' program for the fast analysis of DNA and protein sequences on the Apple Macintosh family of computers, Nucleic Acids Research, 1988, pp. 1829-36, Vol. 16, No. 5. | |
| | | MITANI et al., Rescue, propagation, and partial purification of a helper virus-dependent adenovirus vector, Proc. Natl. Acad. Sci., April 1995, pp. 3854-58, Vol. 92. | |
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(10-03) 1-0031

Substitute for form 1449A/PTO Complete if Known 10/038,271 Application Number INFORMATION DISCLOSURE Filing Date October 23, 2001 STATEMENT BY APPLICANT Fallaux et al. First Named Inventor Group Art Unit 1632 (use as many sheets as necessary) **Examiner Name** D. Nguyen Sheet Attorney Docket Number 2578-3833 6US

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| | 1 | NON PATENT LITERATU | | · | | |
|------------------------|--------------|---|------------------------|--|--|--|
| Examiner Initials * | Cite No.1 | (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), relative issue manifest (s), page(s) | | | | |
| | | PESHWA et al., Cultivation of Mammalian Cells as Aggrega Distribution of Viability, 1993, pp. 179-87, Vol. 41. | tes in Bioreactors: E | Effect of Calcium Concentration on Spatial | | |
| | | PRELICH et al., Functional Characterization of Thermolabile Replication, Journal of Virology, Mar. 1986, pp. 883-92, Vol | - | eins That Affect Adenovirus DNA | | |
| | | RAO et al., The adenovirus E1A proteins induce apoptosis, v Natl. Acad. Sci., August 1992, pp. 7742-46, Vol. 89. | which is inhibited by | the E1B 19-kDa and Bc1-2 proteins, Proc. | | |
| | | RHIM, JOHNG S., Development of Human Cell Lines from pp. 16-25. | Multiple Organs, 200 | 00, Annals New York Academy of Sciences, | | |
| _ | | ROWE et al., Establishment and Characterization of Hamster of Adenovirus 5, Journal of Virology, Jan. 1984, pp. 162-70, | | med by Restriction Endonuclease Fragments | | |
| _ | | RULEY, H. EARL, Adenovirus early region 1A enables vira culture, Nature, August 1983, pp. 602-06, Vol. 304. | and cellular transfo | rming genes to transform primary cells in | | |
| | | SAMBROOK et al., Molecular Cloning A Laboratory Mar Cold Spring Harbor, New York. | nual, 3rd edition, 200 | 01, Cold Spring Harbor Laboratory Press, | | |
| | | WHITE et al., Adenovirus E1B 19-Kilodalton Protein Overcomes the Cytotoxicity of E1A Proteins, Journal of Virology, June 1991, pp. 2968-78, Vol. 65, No. 6. | | | | |
| | | WHITE et al., Role of Adenovirus E1B Proteins in Transformation: Altered Organization of Intermediate Filaments in Transformed Cells That Express the 19-Kilodalton Protein, Molecular and Cellular Biology, Jan. 1990, pp. 120-30, Vol. 10, No. 1. | | | | |
| | | WHITE et al., Specific disruption of intermediate filaments and the nuclear lamina by the 19-kDa product of the adenovirus E1B oncogene, Proc. Natl. Acad. Sci., December 1989, pp. 9886-90, Vol. 86. | | | | |
| | | WHITE et al., The 19-Kilodalton Adenovirus E1B Transforming Protein Inhibits Programmed Cell Death and Prevents Cytolysis by Tumor Necrosis Factor alpha, Molecular and Cellular Biology, June 1992, pp. 2570-80, Vol. 12, No. 6. | | | | |
| | | WOODWORTH et al., Transformation of Differentiated Rat Hepatocytes with Adenovirus and Adenovirus DNA, Journal of Virology, Nov. 1987, pp. 3570-79, Vol. 61, No. 11. | | | | |
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